

**REMARKS/ARGUMENTS**

By this Amendment, claims 32 and 35 have been canceled. Claims 31, 33-34 and 36-38 are pending.

Rejection of Claims under 35 U.S.C. 112, second paragraph

The Examiner states that claims 31-32 and 34-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner states further that claims 31 and 32 are duplicative as are claims 34 and 35. Applicant does not agree with the Examiner that claims 31 and 32 are duplicative or that claims 34 and 35 are duplicative. Nevertheless, Applicant has canceled claims 32 and 35 which should obviate the Examiner's rejection.

Rejection of claims under 35 U.S.C. 112, first paragraph

The Examiner has also stated that the Loeb abstract is not found to be persuasive as it states that more research is needed to investigate these agents (doxycycline and rifampin) and the instant claims have not been limited to the treatment of patients with mild to moderate AD but encompass patients with severe AD. This rejection is respectfully traversed. The statement that "more research is needed to investigate these agents" does not negate the fact that there was "significant" positive effect of antibiotic treatment when tests were taken at 6 months. Positive effects were also seen after 12 months. Furthermore, the study conducted by Loeb et al. which only tested these agents on patients with mild to moderate AD provides a reasonable expectation that there will be at least some positive effect on patients with severe AD.

Rejection of claims under 35 U.S.C. 103(a) and 102(a)

The Examiner has also rejected claims 31-38 as being unpatentable over Shor et al (US Patent No. 5,424,187) in combination with Koskiniemi et al (Eur. Neurol. 1996) for the reasons set forth in the Office Action of July 11, 2003 and in view of Mitchell (which appears critical to the Examiner's position).

The Examiner has not deemed the Applicant's arguments persuasive, because, according to the Examiner, it was known in the art at the time the instant invention was made that Chlamydia infection was associated with Alzheimer's disease as disclosed by Mitchell et al. (US Patent No. 6,664,239; hereinafter referred to as "Mitchell"). Mitchell discloses the treatment of Alzheimer's disease with antibiotics or antibiotics in combination with anti-inflammatory agents. Thus, the Examiner has also rejected claims 31-38 under 35 USC 102(a) as being anticipated by Mitchell and under 35 USC 103(a) as being obvious in view of Mitchell.

Applicant respectfully disagrees with the Examiner and has submitted a Declaration under 37 C.F.R. 1.131 (including Exhibit A) which counters the Examiner's rejection by showing that the conception of the instant invention antedates Mitchell's disclosure. The Mitchell patent claims priority to six U.S. Provisional applications, each of which was filed on May 6, 1997. After examining the file histories of each of these U.S. provisional applications, Applicant has determined that Mitchell did in fact disclose Alzheimer's disease as a disease linked to infection by an intracellular pathogen in each of these provisional applications. Thus, the earliest date of Mitchell's disclosure is May 6, 1997. Applicant's attached Declaration, however, confirms that conception of the instant invention took place prior to May 6, 1997. Applicant has submitted as proof of conception a letter of recommendation (See Exhibit A) written by Brian J. Balin, Ph.D., a co-inventor of the instant invention, to Evelyn J. Ford at the AUHS Institute for Neurosciences. In his letter, which predates May 6, 1997, Dr. Balin makes it very clear that the focus of the work in his laboratory is to study the role *Chlamydia pneumoniae* plays as an infectious agent in the pathogenesis of Alzheimer's disease. He also states that recent findings in his laboratory led his graduate student, Mr. Arking, to concentrate his thesis project on this area of research. Because Applicant has shown that the instant invention was conceived prior to Mitchell's May 6, 1997 date, it follows the Examiner's rejections are not valid.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Application No. 09/227,749  
Reply to Office Action of March 2, 2004

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

September 2, 2004

Please charge or credit our  
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By



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